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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/713,530

11/13/2003

Andrew Thomas Forsberg

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10/15/2008

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EXAMINER

GETTMAN, CHRISTINA DANIELLE

ART UNIT

PAPER NUMBER

3734

MAIL DATE

DELIVERY MODE

10/15/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/713,530	Applicant(s) FORSBERG ET AL.	
	Examiner CHRISTINA D. GETTMAN	Art Unit 3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 June 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4,5,7,12-16,20-22,24,25,28,33-39 and 45-60 is/are pending in the application.
- 4a) Of the above claim(s) 4,5,7,12,22,24,25 and 33-39 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,13-16,20,21,28 and 45-60 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>06/18/2008</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 27, 2008, has been entered.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on June 18, 2008, was filed after the mailing date of the Final Rejection on March 27, 2008. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 56 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 56 recites "wherein the first inlet port is in the distal end of the insertion sheath" in lines 1-2. Applicant recites in claim 47, which claim 56 is dependent from, "a

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first inlet port located in the distal end of the dilator." It is unclear how the first inlet port can be located in the distal end of both the insertion sheath and the dilator.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 13-16, 20, 21, 28, and 45-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kensey et al. (U.S. Patent No. 6,179,863) in view of Ginn et al. (U.S. Patent NO. 6,626,918). Kensey et al. disclose the invention substantially as claimed including an insertion sheath (ref. 28), a dilator (ref. 400), a first hole (ref. 404) on the dilator, a second hole (ref. 304) on the sheath, a first indicator (ref. 406 leads to ref. 28D), a second dilator (lumen between ref. 28 and 400 leads to ref. 28D), the dilator extending past the distal end of the insertion sheath (see Fig. 27), and the holes determining the position of the device relative to the blood vessel. Kensey et al. discloses that a first lumen is defined in the dilator and a second lumen is defined in the sheath, in-between the dilator and sheath. Although Kensey et al. disclose two separate embodiments for determining the location of the sheath relative to the vascular puncture (a hole on the dilator or a hole on the sheath), it would have been obvious to combine the two in order to have a locator before and after the edge of the introducer sheath. This would allow for the user to more easily determine where the edge of the introducer sheath is relative to the vascular puncture. Kensey et al., however, do not disclose

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using two separate indicator ports. Ginn et al. disclose an insertion sheath (ref. 312), a dilator (ref. 314), a first hole (ref. 342) that is axially aligned with a second hole (ref. 350), a first indicator (ref. 247), a second indicator (ref. 251), a first lumen (ref. 348) allowing for fluid communication between the first hole and the first indicator, and a second lumen (ref. 352) allowing for fluid communication between the second hold and the second indicator for the purpose of determining the distance the device has traveled into the vascular puncture and vessel. It would have been obvious to one having ordinary skill in the art at the time of the invention to have modified the device of Kensey et al. with two holes and two separate indicator holes in order to determine the point right before the introducer sheath enters the vessel and the point right after the introducer sheath enters the vessel.

Response to Arguments

Applicant's arguments with respect to claims 1, 13-16, 20, 21, 28, and 45-60 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTINA D. GETTMAN whose telephone number is (571)272-3128. The examiner can normally be reached on Monday-Thursday 6:45 am to 3:15 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on 571-272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Christina D Gettman/
Examiner, Art Unit 3734
571-272-3128

/Todd E Manahan/
Supervisory Patent Examiner, Art Unit 3731